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09/936,534	02/03/2003	Catia Bastioli	13929/T/B/A	7100
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Byran Cave LLP 1290 Avenue of the Americas 33rd Floor New York, NY 10104			EXAMINER SAYALA, CHHAYA D	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

09/936,534

**Applicant(s)**

BASTIOLI ET AL.

**Examiner**

C. SAYALA

**Art Unit**

1794

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 4, 7 and 10-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 7 and 10-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/02)
- Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by EP 011663.

Claim 14 claims a mixture of inulin and /or oligofructan with thermoplastic polymers.

See the claims in the EP patent. See claim 1 which shows a tubular membrane prepared as in claims 3, 5 and 8, which claims are pertinent to the extent of their disclosure of the mixture claimed herein, i.e. polymer and inulin, capable of being extruded.

2. Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/09176.

See claims 1-5. Claim 1 describes a polysaccharide given as inulin in claim 5, which contains a moiety which will undergo polymerization. Therefore, the material is a combination of inulin and a polymer and is "thermochemically processable".

3. Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Guttag (US Patent 5346929).

See claims 1 and 11 that recite inulin with polymers. "Chewable article for animals" is use terminology. See In re Zierden, 162 USPQ 102, In re Jones, 50 USPQ 48, In re Spada, 15 USPQ 2d, 1655, In re Thuau 57 USPQ 324. Since inulin is the same, then it is inherently "thermoplastically processable".

Claim 1 recites a synthetic polymer and a natural polymer, which claim 11 recites is an inulin, synthetic polymers described at col. 4, lines 10-16. The claim requires two elements, inulin and thermoplastic polymers.

4. Claim 14 is rejected under 35 U.S.C. 102(e) as being anticipated Van Haveren et al. (US Patent 6313203).

The claims show a mixture of a thermoplastic polymer with inulin. See claim 4. See col. 2, lines 10-11 that describe inulin as being the polyfructose (claim 1), which is a known fact in basic chemistry.

***Claim Rejections - 35 USC § 103***

5. Claims 1, 4, 7, 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leo (US Patent 5419283) and Wang (US Patent 5922379) in view of Anantharaman et al. (US Patent 5952033) and further in view of Van Haveren et al. (US Patent 6313203) and Bengs et al. (US Patent 6406530).

Both Leo and Wang teach biodegradable thermoplastic products.

Leo discloses a chew toy for pets made from a plastic material. At col 1, lines 27+ patentee states:

The preferred materials are thermoplastic blends obtained by processing starch and said thermoplastic polymers in the presence of a limited amount of water (10-40% wt. referred to

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the starch/water system) or of a polyol plasticizer (10-40% wt. referred to the starch/polyol system), under extrusion cooking conditions thereby to provide a melt to be extruded and transformed into pellets for use in injection moulding or to be directly injection moulded.

At col 1, line 33-40 states that the materials thermoplastic blends of starch and thermoplastic polymers in the presence of water and polyols as plasticizers, can be extruded.

Wang teaches a biodegradable protein/starch based thermoplastic composition that can be extruded and consumed by animals. See col 8, lines 13-14, col 2, line 17. Plasticizers are shown at col 4 line 46+. The amount of starch is 20-60% (col 3, lines 63-64).

Both patents do not teach inulin. However, inulin, a polysaccharide, is known to be a stabilizer for extrudable thermoplastics. See Van Haveren et al (col 2, line 62-64 and abstract). Also, Bengs et al. teach a mixture of starches including inulin, used in biodegradable thermoplastic materials that can be thermoplastically processable using techniques such as injection holding or extrusion. Col 1, line 32, col 2, lines 58, col 3, lines 20-21, col 4 line 66-67, col 5, lines 21-28. Note that the *mixture* of starches is given to be in an amount 33-90%.

Anantharaman et al teach the use of inulin in pet food products is beneficial in an amount of at least 0.25%. See col 1, which states that inulin promotes bifido- and lacto-bacteria in the GI tract at the expense of pathogens and is very beneficial for animals and inulin has been used as a vet diet for pets. Col 1, 50-52. col 2, lines 7-12. This patent establishes that inulin has been used for pet foods and that "for pet foods,

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their use has been confined to specialty veterinary products such as the Eukanuba product and to pet treats. Similarly, for human foods, their use has been confined to specialty products." (Col. 2, lines 7-10).

Therefore, while Leo and Wang establish biodegradable, thermoplastically processable starch containing products have been used for pet chews, Anantharaman et al., by establishing that inulin provides benefits for the GI tract for pets, and that inulin has been used for pet treats, motivates one of ordinary skill in the art to incorporate inulin in biodegradable, thermoplastically processable products of Leo and Wang in pet products with plasticizers or glycerol, etc. In fact the patents to Bengs et al. and Van Haveren et al. show shaped, extrudable, biodegradable, inulin containing articles wherein inulin additionally acts as a stabilizer for such a thermoplastically processable compositions (Van Havernan et al.). Patents to Anatharaman et al. and Van Haveren et al. show inulin amounts of "at least 0.25%" and mixtures of starch including inulin between 33% to 90%, and to determine amounts for various pet chew articles would have been obvious based on such disclosure. With regard to claim 13, Leo shows a bone. With regard to claim 12, the Anantharaman et al. patent shows the extrusion temperature at col 4, line 10-15.

Summarizing:

- Leo teaches the use of thermoplastic blends of starch and polymers and polyols as plasticizers, extruded to a chew toy.

- Wang et al. teach biodegradable protein/starch thermoplastic compositions that can be extruded and consumed by animals.
- Anantharaman et al. teach the usefulness of inulin in pet foods and disclose that it has been used as a vet diet for pets.
- Van Haveren et al. disclose that inulin is a stabilizer for extrudable thermoplastics.
- Bengs et al. teach a mixture of starches including inulin, in a composition that is thermoplastically processable using extrusion techniques and injection molding.

### ***Response to Arguments***

Applicant's arguments filed 2/11/2008 have been fully considered but they are not persuasive.

Applicant, in every case, with regard to the 35 USC 102 rejections has said that the rejection has not been explained with regard to "page and line" number. First, there are no page numbers, only column numbers and then, the claim rejected in these rejections is only claim 14 that requires only two elements: inulin and "thermoplastic polymers". The rejections have been made over a minimal number of claims in the references. Nonetheless, the Office action has now been revised to further expand on these rejections, as expediently as can be done in the time stipulated and allowed for each case. If further explanation is required, applicant is respectfully urged to request such.



Next, applicant has urged that the following description from the specification be read into the claims in order to distinguish the claimed product, and to render these claims patentable (for instance at page 7, 3<sup>rd</sup> full paragraph of his response):

“the fact that inulin and its mixtures with thermoplastic polymers are rendered thermoplastically processable **because the extrusion is conducted in the presence of water and/or plasticizer containing hydroxyl groups at temperatures of between 80 and 200°C.** (See, e.g., Specification at page 4, line 24 to page 5, line 3 and claim 12.).”

However, it is well established that

Although a claim should be interpreted in light of the specification disclosure, it is generally considered improper to read limitations contained in the specification into the claims. See *In re Prater*, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969) and *In re Winkhaus*, 527 F.2d 637, 188 USPQ 129 (CCPA 1975), which discuss the premise that one cannot rely on the specification to impart limitations to the claim that are not recited in the claim.

With regard to "Goehl", applicant states that the patentee extrudes to obtain a sheet and the sheet does not contain inulin in the thermoplastically processable form. The claim as recited, states a mixture of inulin and thermoplastic polymer, which is shown by the patent at claim 2 and claim 8. "Thermoplastically processable" is not only part of the preamble but when given the ordinary dictionary meaning (see PTO-form 892 which provides the Dictionary page), translates to being capable of being processed thermoplastically. Therefore, the claim is met by this patent. Applicant's position that inulin is a swelling agent is irrelevant, because if inulin is a swelling agent in the reference, then it must be a swelling agent in the application as well, since a compound and its property cannot be separated. See *In re Papesch*, 137 USPQ 43

(CCPA 1963). Furthermore, inulin being a swelling agent does not take away from the fact that it is present in the combination of the reference. Applicant is reminded that this is a product claim and not a process claim.

Soon-Shiang has been criticized for disclosing a biocompatible material and not a "chewable" article. If the two elements claimed are present, then they must be capable of being chewed on as well, and therefore, must be "chewable". Finding one more property, i.e. of being "chewable" does nothing to a combination already known and old in the art.

The criticism of Gutttag runs along the same lines: 1) that the examiner has not provided a detailed explanation of the reference based on the single claim (14) of two elements, 2) that the examiner must import the limitation regarding extrusion from page 4, page 5 of the specification into claim 14 and 3) that Gutttag does not disclose "a chewable article" but shows bowls, boxes, dishes, etc and 4) that the reference shows a microorganism. In addition to the points 1-2 already discussed with regard to the other reference rejections, and therefore applicable here too, Gutttag disclosing the utility of the product does not establish patentability of the instant claims because it is well established that applicant finding a new utility for an old composition does not lend patentability to the old composition. See In re Zierden, 162 USPQ 102, In re Jones, 50 USPQ 48, In re Spada, 15 USPQ 2d, 1655, In re Thuau 57 USPQ 324.

Finally, the claim recites the transitional phrase "comprising" which does not exclude any other element such as a microorganism.

Regarding the 35 USC 102(e) rejection over the Van Haveren reference and the Bengs reference and the only 35 USC 103 rejection made here, applicant has stated that these rejections are improper because his application claims an Italian priority date of March 15, 1999. The file wrapper of this case has been thoroughly reviewed and it cannot be said that applicant has perfected his foreign priority date. Until such time, the rejections made over these references (Van Haveren and Bengs) are deemed proper and valid and cannot be withdrawn.

At page 19 of his response, applicant has held that the rejection contains only conclusory statements and does not provide motivation to modify the primary references. A summary of the rejection was provided for easy comprehension, in the Office action thus:

- Leo teaches the use of thermoplastic blends of starch and polymers and polyols as plasticizers, extruded to a chew toy.
- Wang et al. teach biodegradable protein/starch thermoplastic compositions that can be extruded and consumed by animals.
- Anantharaman et al. teach the usefulness of inulin in pet foods and disclose that it has been used as a vet diet for pets.
- Van Haveren et al. disclose that inulin is a stabilizer for extrudable thermoplastics.
- Bengs et al. teach a mixture of starches including inulin, in a composition that is thermoplastically processable using extrusion techniques and injection molding.

The references of Van Haveren and Bengs provide strong motivation to modify the primary references that already disclose thermoplastic polymers. Further Anantharaman shows that inulin provides an additional benefit. While applicant insists that his invention is unobvious because the extrusion was conducted with water and/or a plasticizer, the references clearly establish that there was sufficient motivation to combine them, as stated above. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Again, applicant is reminded that the terms "processable" and "chewable" are interpreted as being "capable of" being processed or chewed, respectively. And again, the claims herein are to a product and not to a process. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

At page 21, applicant has stated that the Examiner "has yet to come to grips with these glaring factual differences". While such language is strenuously taken objection to, it is being emphatically stated that it is applicant who has to come to grips with the fact that these are product claims, and it is being emphasized that claims 12 and 7 are to "A chewable product", i.e. a product that has the capacity to be chewed, and it is the

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novelty of the product that needs to be established and not of any process step, and particularly any that is to be imported into the claims from the specification.

Furthermore, the rejection was made over 5 references, and if applicant has chosen to delete 2 references from the rejection, based on his own improper reason, not only will the rejection appear to him as lacking motivation but also that the examiner lacks the ability to come to grips "with these glaring factual differences". "Assertion that examiner combines prior art references for purpose different from that envisioned by inventors does not warrant reversal of examiner's finding of obviousness". Ex parte Raychem Corp., 17 USPQ2d 1417.

Finally, applicant has also included the "improper hindsight reasoning" argument, in response to which, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

No claim is allowed.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **C. Sayala, Ph.D.** whose telephone number is (571) 272-1405. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

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have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/C. SAYALA/**

**Primary Examiner, Art Unit 1794**